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A COMPARISON OF PHARMACEUTICAL REIMBURSEMENT AGENCIES' PROCESSES AND METHODS IN FRANCE AND SCOTLAND

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Objectives: Pharmaceutical reimbursement agencies' processes and methods of appraisal vary across countries. The objective of this study was to examine the contribution of formal health economic analysis in a process using such analysis in Scotland in comparison to a process not routinely using such analysis in France.
Methods: A framework for classifying reimbursement systems was used to analyze the two systems. A typology of recommendation was defined and a qualitative analysis of decisions on a sample of medicines appraised by both reimbursement agencies was conducted. Reasons for differences in recommendations were analyzed and case studies selected to illustrate the common reasons.
Results: Thirty-nine common medicines appraised by both agencies were identified between 2005 and 2010, treating a variety of diseases for which the Scottish Medicines Consortium tended to provide more restrictive, or did not recommend, listing. Similarities in clinical evidence submitted to the respective reimbursement committees were observed. Differences in recommendation can be explained by a combination of the manufacturer's freedom to set price and the incentives provided by the consideration of health economic analysis and quality of life, alongside differences in relevant comparators, relevant outcomes, treatment guidelines, and the propensity to use network meta-analysis, in decision making.
Conclusions: This study provides some explanations and hypotheses for the differences observed in recommendations for a selected sample of medicines with regards to differences in appraisal processes and methods adopted. Further research using larger datasets may allow stakeholders to assess the impact of such differences on the efficient use of health resources.

Keywords: Reimbursement, Medicines, Economic evaluation, Scottish Medicines Consortium, Haute Autorité de santé, JEL I18, government policy, regulation, public health

Governments intervene in pharmaceutical markets to promote health and affordable access to pharmaceuticals, while balancing the Research and Development (R&D) incentive for global pharmaceutical companies to invest in future medicines (15). On the demand side, the collective systems of pricing and reimbursement are one means by which these objectives can be achieved. Healthcare systems differ in the complexity of processes they follow and the evidence they require from manufacturers when appraising new pharmaceuticals for inclusion in their public formulary. Most developed countries require a form of health technology assessment (HTA) when appraising new medicines, to consider evidence on clinical effects and costs, and twenty of thirty-four OECD countries report that they require health economic analysis in the manufacturer's submission. One exception is the French reimbursement agency, the Haute Autorité de santé (HAS), which does not require a health economic analysis for new medicines and separates costing issues from consideration of the clinical-efficacy and relative-effectiveness of medicines.[1]

Previous studies have provided comparisons of the influences on reimbursement recommendations for a limited number of OECD reimbursement agencies that have similar evidence requirements (1;2;4;10;19). This literature has focused on comparisons of decisions and the contribution of clinical and economic evidence by the National Institute for Health and Clinical Excellence (NICE) in England, Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada and the Scottish Medicines Consortium (SMC) in Scotland.

The impact of differences in reimbursement agencies' processes and evidence requirements on the reimbursement recommendations across countries is largely unknown. Studies have identified that more research is required into the use of evidence and HTA and its linkage with policy making in countries by conducting more detailed comparative studies of different countries decision making (4;9;14). This study considers the contribution (alongside identified process differences) of health economic analysis to the appraisal and recommendations of

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[1] The agency established the Commission évaluation économique et de santé Publique (CEESP) following a new law in 2008 requiring HAS to start considering the methods of medic-economic evaluations and provide these for selected medicines but is not currently used across all new medicines when the clinical efficacy/effectiveness is appraised.

the SMC in Scotland in comparison to HAS in France, which only requires clinical evidence. An understanding of the relative impact of the use of health economic analysis and agencies' process differences on recommendations will help stakeholders identify best practices for these reimbursement agencies, given their objectives and healthcare system context.

OBJECTIVES

The objective of this study was to compare the medicine reimbursement systems in France and Scotland and specifically to examine the contribution of health economic analysis, alongside any differences in the agencies' processes on the reimbursement recommendations for medicines appraised.

METHODS

This study was based on a detailed review of relevant literature and documents, supplemented by consultations with staff members of the agencies and researchers active in the HTA field in France and Scotland. The first step was to obtain a clear picture of the operation of each reimbursement decision-making system from published commentaries and the publicly available documents. The differences in processes and decision criteria were identified using a framework for describing and classifying reimbursement systems (9). The framework classifies systems at a policy implementation level and technology decision level.

The listing recommendations of both agencies were classified using a modification of a categorization developed by Raftery (18), which distinguishes between the different types of restriction. The classification included; recommend in line with marketing authorization, minor restriction (specialist use/monitoring of patient), major restriction (limited to line of therapy, patient subgroup, intolerant to existing treatments) and not recommended. The classification additionally accounted for the type of HAS recommendation either for National Insurance and hospital use or hospital use only.

The distribution of recommendations across the categories for each agency was assessed by classifying all recommendations published in 2010. To provide explanations for differences in recommendations between the two agencies, detailed documentation of decisions is needed. This is available in English translation for a limited number of medicines appraised by HAS. To increase the sample for analysis, the HAS English language translated opinion documents were extracted from the HAS Web site for recommendations between 2005 and 1st of January 2010 and were matched with SMC advice for the same medicine and patient indication. The HAS agency prioritized the translation of advice by those medicines that had gained a European Marketing Authorisation (EMA) and there were no major changes to either agencies' evidence requirements or processes during this period. The type of data extracted from the SMC and HAS recommendation documents are presented in Table 1.

Data were collected on the characteristics of the evidence and committees' perceptions of its fitness for purpose. A qualitative analysis of the documentation was performed to identify themes for differences in the agencies' recommendations. This was achieved by coding the main themes in each pair of matched advice with respect to the common reasons for differences in the recommendations. Three medicines were selected to illustrate common reasons for differences between the recommendations of the two agencies.

RESULTS

The results are presented in two sections: (i) Classification using the framework (part 1); (ii) Comparison of the recommendations for a series of medicines appraised by both agencies (common medicines) (part 2).

Part 1: Comparison of Reimbursement Systems

Figure 1 illustrates the reimbursement systems and Supplementary Table 1 (which can be viewed online at www.journals.cambridge.org/thc2012019) provides the detailed results. Both agencies aim to provide advisory recommendations to their respective institutions using elements of HTA but operate in complex reimbursement systems that share similarities and differences.

The Scottish health system, which is financed predominantly by taxation, has a two-stage approach whereby the central reimbursement recommendation is based on the price provided by the manufacturer (with or without a Patient Access Scheme (PAS)). Launch prices are set freely and expenditure is restricted by ex-post profit control and price reductions though the United Kingdom wide Pharmaceutical Price Regulation Scheme (PPRS) (6). The final formulary inclusion decision is made by local Health Boards using the SMC advice.

The French system is financed through social health insurance and operates in a three-stage approach, involving two separate institutions, where the reimbursement recommendation is provided by HAS through its Transparency Committee (TC), price and volume agreements are negotiated by the Economic Committee for Health Products (CEPS) and the final reimbursement decision is made by the Ministry of Health (7;11).

HAS appraises all medicines whereas the SMC appraises a narrower remit of new medicines. Both require the manufacturers to provide all relevant evidence of clinical-efficacy, safety, and clinical-effectiveness and allow Network Meta-Analyses (NMA) (20). The main difference in the evidence requirements is the lack of demand for a formal health economic analysis by HAS. The SMC requires the manufacturer to demonstrate the cost-effectiveness of the medicine and explore any associated uncertainty in the analysis (20;21).

The TC and SMC use different approaches to appraising the evidence. The SMC provides a qualitative description of the clinical evidence and estimates of cost-effectiveness submitted. The medicines incremental cost-effectiveness ratio (ICER), expressed in terms of cost per quality-adjusted life-year (QALY) gained, is considered as one factor when providing the

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Table 1. Description of Data Extracted From Medicine Reimbursement Recommendation Documentation

Item	Data extracted	Notes regarding extracted evidence
Listing Recommendation	• Listing recommendation reported in advice documents; • Type of use for recommendation for France (Hospital use or Social Health Insurance); • Disease area.	The recommendations for both agencies were extracted for classification into one common classification provided by Raftery et al.
Manufacturers submitted clinical evidence	• Clinical efficacy evidence (trial name and year); • Evidence Synthesis (meta-analysis, network meta-analysis); • Comparators; • Primary Outcome.	Data were collected from the recommendation documents to identify the clinical efficacy evidence and evidence synthesis. Trial names were identified from Cochrane CENTRAL database.
Fitness for purpose of clinical evidence and evaluation of relative-effectiveness:	• Reported issues with clinical evidence submitted; • Conclusions regarding relative effectiveness of the medicine; • SMR (medical benefit); • ASMR (improvement in medical benefit).	The fitness for purpose of the manufacturers submissions were assessed by statements reported in the documentation with regard to the committees' issues with the clinical evidence with respect to study design, quality, relevance to practice, and robustness of network meta-analysis. The conclusions regarding the relative-effectiveness through the description provided by the SMC and the HAS judgement of the ASMR resulting from the evidence.
Manufacturers health economics submission	• Type of health economic evaluation; • Cost-effectiveness estimate reported.	The estimates of cost-effectiveness analysis were recorded for those specific to the indication recommended in the advice document.
Fitness for purpose of health economic evaluation.	• Reported issues with health economic evaluation submitted to the SMC; • Conclusion regarding cost-effectiveness.	The fitness for purpose of the manufacturers health economic evaluations were assessed by the main issues reported in the SMC recommendations documentation.

recommendation. The ICER threshold range reported by NICE is taken into consideration alongside other criteria (12). In contrast, the TC members vote for a categorical assessment of the medical benefit (Service Médical Rendu, SMR) and improvement in actual benefit (L'amélioration du Service Médical Rendu, ASMR) (Supplementary Table 1).

If initially rejected, the manufacturer may resubmit to the SMC in the presence of new evidence or a new analysis of the evidence but there is no periodical review. In contrast, HAS can self-refer; manufacturers can submit new evidence and all medicines are re-appraised at 5 years post-listing. The reappraisal may result in a revised SMR and delisting in France.

Part 2: SMC and HAS Recommendations

In 2010, HAS published a total of 410 opinions (excluding simplified process) on their Web site and SMC published 86 advices (including abbreviated submissions). This reflects the wider remit of HAS and reassessment of SMRs. As Table 2 and Supplementary Table 2 (which can be viewed online at www.journals.cambridge.org/thc2012019) show, HAS appears to recommend listing more frequently than SMC.

Matched Sample of Medicine Recommendations

For the detailed analysis of decisions, thirty-nine HAS English translated submissions were matched between 2005 and the start of 2010 (Table 3). The medicines treated a variety of diseases and details are provided in Supplementary Tables 3 and 4 (which can be viewed online at www.journals.cambridge.org/thc2012019). The proportions of medicines recommended for listing in this selected sample of medicines were 85 percent for the SMC and 100 percent for HAS. There were fourteen concordant decisions made between the two agencies (Kappa Statistic = 0.11), which can be interpreted as low agreement between the agencies' recommendations. The TC requested additional observational data as a condition for eight recommendations.

Clinical Evidence Submitted

The majority of submissions contained one or two key trials demonstrating the clinical-efficacy. There was at least one commonly reported trial in both the SMC and HAS recommendation documents for each medicine. In twelve of the recommendations there were additional studies presented by the manufacturers to one agency over the other agency. There were six cases where no common comparators were shared between the submissions

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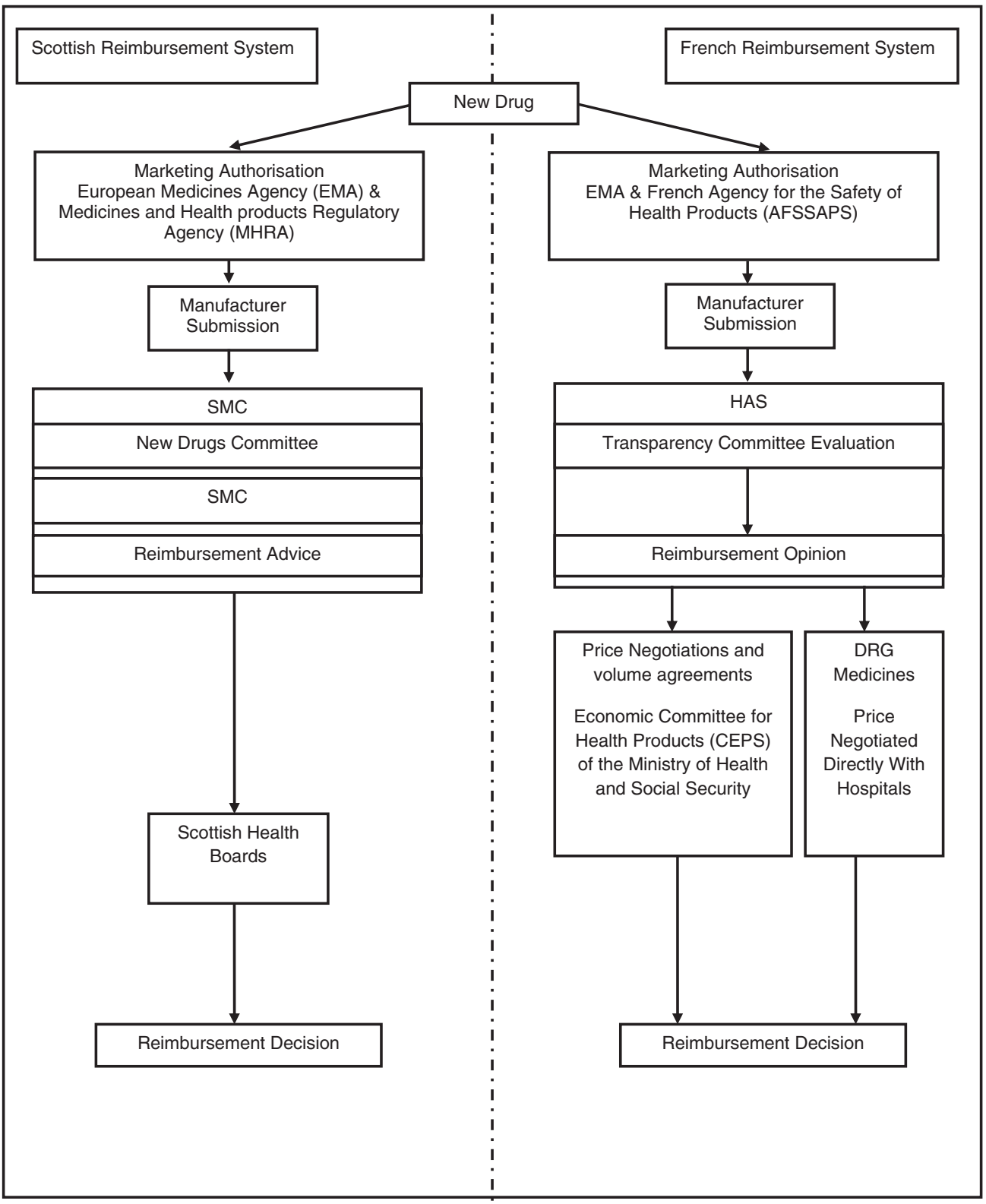

Figure 1. Reimbursement system.

for SMC and HAS. NMA were present in eight submissions to the SMC and three submissions to HAS. Both agencies provided few details of the NMA such as the trials included, type of comparison and statistical analyses.

Both committees reported issues with the clinical evidence in 77 percent (30/39) of submissions, most commonly, the lack of active comparators ($n = 14$) and the selection of trial population ($n = 9$). NMA submitted to HAS were all judged unreliable

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Table 2. 2010 Recommendations by Haute Autorité de santé (HAS) and Scottish Medicines Consortium (SMC)

	HAS - 2010	SMC - 2010
Recommendation by type		
Recommendations (all submissions on Web site excluding HAS simplified procedure)	410	86
Recommendations subset (Full submission for new medicine, indication, extension)	122 (30%)	57 (66%)
Recommendations for new medicine, indication or extension		
Recommended listing (including major/minor restriction)	115 (94%)	32 (56%)
Not recommended listing	7 (6%)	25 (44%)
Common appraisals		
Common appraisals for new medicine, indication or extension	17 (14%)	17 (30%)
Disease treated (ICD 10 codes by chapter)		
Certain infectious and parasitic diseases	15 (12%)	1 (1%)
Neoplasms	16 (13%)	17 (30%)
Diseases of the blood and immune mechanism	6 (5%)	4 (7%)
Endocrine, nutritional, and metabolic diseases	9 (7%)	8 (14%)
Mental and behavioral disorders	4 (3%)	2 (4%)
Diseases of the nervous system	9 (7%)	2 (4%)
Diseases of the eye and adnexa	4 (3%)	1 (2%)
Diseases of the circulatory system	16 (13%)	5 (9%)
Diseases of the respiratory system	5 (4%)	3 (5%)
Diseases of the digestive system	7 (6%)	1 (2%)
Diseases of the skin and subcutaneous tissue	3 (2%)	4 (7%)
Diseases of the musculoskeletal system and connective tissue	4 (3%)	6 (11%)
Diseases of the genitourinary system	2 (1%)	0 (0%)
Pregnancy, childbirth, and the puerperium	1 (1%)	0 (0%)
Certain conditions originating in the perinatal period	1 (1%)	0 (0%)
Congenital malformations and chromosomal abnormalities	1 (1%)	0 (0%)
Symptoms, signs, and abnormal clinical and laboratory findings	4 (4%)	2 (3%)
Injury, poisoning, and certain other consequences of external causes	2 (2%)	0 (0%)
Factors influencing health status and contact with health services	13 (11%)	1 (1%)

Table 3. Cross Tabulation of Matched Scottish Medicines Consortium (SMC) Advice and Haute Autorité de santé (HAS) Opinions

	HAS advice				
SMC advice	To list advice	To list minor restriction	To list major restriction	To not List	Total (SMC)
List advice	8	3	2	0	13 (33%)
List minor restriction	1	4	0	0	5 (13%)
List major restriction	11	2	2	0	15 (39%)
To not listed	3	2	1	0	6 (15%)
Total (HAS)	23 (59%)	11 (28%)	5 (13%)	0 (0%)	39 (100%)

due to the lack of exchangeability between trials. In contrast, the SMC considered all NMA used in the economic models submitted (some also informed NICE decision making).

The TC considered 64 percent (24/39) of medicines submitted to demonstrate relative-effectiveness (ASMR = 1,2,3,4) and it was inferred from the description that the SMC judged improvement in clinical-effectiveness for thirty medicines (Supplementary Table 5, which can be viewed online at www.journals.cambridge.org/thc2012019).

Economic Evidence Submitted

The SMC reported issues with the economic evidence in 21 submissions, most frequently: the number of comparators considered ($n = 5$), costing and resource use ($n = 5$), model assumptions ($n = 4$), and the clinical data ($n = 3$). Cost-utility analysis was submitted in thirty-one cases claiming an improvement in health-related quality of life (HRQOL) in comparison to usual

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practice in Scotland and a subgroup was targeted in eleven submissions (with ICERs ranging from dominant to £318,283 per QALY). One submission included a cost-effectiveness analysis and eight submissions included a cost-minimization analysis.

Qualitative Analysis of Reasons for Differences:

The most common reasons for differences were variation in the comparators between countries, and in the committee's judgment of the uncertainty in the evidence. Where there was agreement on the clinical evidence the additional economic evidence considered affected recommendations in various ways. If the economic evidence were uncertain then SMC made a more restrictive recommendation; if the economic analysis identified additional HRQOL benefits then SMC's recommendation was more positive; and if the UK price were relatively high then the medicine was only cost-effective in a restricted sub-group of patients (Supplementary Table 6, which can be viewed online at www.journals.cambridge.org/thc2012019). The following three case studies focus on recommendations in the 2nd and 3rd column of Table 3 to describe some of the common themes that may explain differences.

Infliximab: Synthesis of Evidence Using NMA

The TC opinion included judgments on two extensions of indications (psoriatic arthritis and psoriasis). The SMC advice focused on a single indication for the treatment of moderate to severe psoriasis in adults who have failed to respond to, or who have a contraindication to, or are intolerant of other systematic therapy. The clinical evidence submitted to the SMC and HAS contained the same clinical-efficacy evidence for two double blind RCTs and one additional double blind RCT. Both submissions included an indirect comparison, which was judged by the TC to be unreliable due to the dosage of methotrexate in the included trials, other treatments, lack of tests for heterogeneity, length of follow-up and lack of a systematic review. The TC concluded that infliximab shared the same moderate improvement in actual benefit as etanercept (ASMR = 3) for those patients with severe psoriasis. The TC additionally requested a representative observational study of the benefit in practice over 5 years. The SMC judged the indirect comparison submitted (previously been used in NICE decision making) to be useful for the economic model but noted potential heterogeneity between trials. The results of the indirect comparison found infliximab to have a higher PASI75 response than etanercept and efalizumab. These estimates were included in the economic model producing an estimate of £27,354 per QALY for severe psoriasis. The SMC judged that the economic case had been made for use in a subgroup (major restriction).

Sorafenib: Clinical-Effectiveness Versus Clinical- and Cost-Effectiveness

Sorafenib is indicated for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon alpha or interleuken 2 based therapy or considered unsuitable for such therapy. The same clinical-efficacy evidence was submitted to the agencies, including one Phase II RCT placebo controlled and one Phase III placebo controlled RCT. The trials demonstrated a progression free survival of approximately 3 months in comparison to placebo (relevant comparator in both countries), although evidence was unavailable at the time of recommendations for improvement in overall survival. HAS acknowledged this uncertainty and judged the medicine to be an important improvement in actual benefit (ASMR = 2) and recommended listing. The SMC committee similarly judged an improvement in clinical-effectiveness and considered the manufacturer's Markov model to be well conducted, which produced a base case estimate of £35,523 per QALY. The committee were concerned with the uncertainty in the extrapolations from the available trial data and substantially reduced the confidence that could be placed in the longer-term estimates of cost-effectiveness. The SMC judged that in light of the uncertainty and price supplied that the medicines cost-effectiveness had not been demonstrated.

Erlotinib: Formal Consideration of HRQOL Versus ASMR

Erlotinib is indicated for the treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) after failure of at least one prior chemotherapy regimen (EGFR positive patients only). Both of the submissions included a Phase III double blind placebo controlled trial, in addition the submission to HAS included two phase I dose ranging studies and one phase II non-comparative study of efficacy and safety. The primary outcome of overall survival demonstrated a 2-month improvement in actual benefit in comparison to placebo, but there were other relevant comparators in France and Scotland such as docetaxel and pemetrexed. The absence of evidence against these relevant comparators, led the TC to advise recommendation with no improvement in actual benefit for second line therapy (ASMR = 5). The SMC manufacturer's submission presented the economic case for those that would be eligible for docetaxel monotherapy. The submission presented a cost-utility analysis that was informed by the synthesis of evidence by an indirect comparison to enable a comparison with docetaxel. The analysis found a utility gain for Erlotinib in contrast to the TC, which was unwilling to judge the impact in the absence of direct comparisons. The estimate of £4,800 per QALY in the basecase was subject to uncertainty regarding the appropriate number of cycles for which expert advice considered four to be appropriate resulting in an estimate of £22,500 per QALY. The medicine was recommended by the SMC for the docetaxel-eligible group.

DISCUSSION

The agencies share similarities in their objectives of providing advice to their respective authorities. The HAS recommended listing in the majority of cases, whereas the SMC was more likely to not recommend or place restrictions on medicines

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appraised in 2010. In the common medicines covering a variety of disease areas, the trend remains, although there is a slightly higher proportion of listing recommendations for both agencies in this selected sample. Some of the differences in the recommendations can be explained by local differences in clinical guidelines and comparator treatments.

In using the documentation to determine the impact of the use of health economic analysis on differences in recommendations, an important factor emerged from the organizational analysis of the French and Scottish reimbursement systems—the difference in the method of price determination. Pricing approaches differ between the countries—in France price negotiations are performed by the CEPS after the HAS makes a judgment on the SMR and relative-effectiveness in France (ex-post price negotiation). In contrast, in Scotland prices are set freely (ex-ante free pricing) and an economic analysis provided in addition to show cost-effectiveness at the manufacturer's chosen price. Global profit maximizing manufacturers consider the impact of the listing price in any country on other markets (through international price referencing and parallel importing) as well as on local sales. Traditionally, it has been the view that manufacturers prefer to maintain prices in the UK at higher levels than those maximizing revenue in the local market (3). (Such decisions have been made more complex by the impact on relative European prices of recent declines in the pound sterling/euro exchange rate.) Some support for this view emerged from the findings of this study. In the common medicines appraised there were cases where HAS recommended for its full marketing authorization (leading to a maximum price defined by the ASMR) but the manufacturer chose to submit the cost-effectiveness evidence for a targeted subgroup to the SMC (see erlotinib and infliximab case studies).

In examining the evidence considered by HAS and SMC, similarities were found in the clinical trials submitted by the manufacturer and in the issues raised by each agency in relation to the studies submitted. However, differences in dealing with uncertainty in the clinical data were apparent in some cases, partly driven by the needs of the economic analysis. NMA were more frequently submitted to the SMC and included in the respective economic analysis, alongside sensitivity analysis to explore the uncertainty in the treatment effect. The TC usually rejected NMA as insufficiently robust and adopted a conservative approach to categorizing the medicine as no improvement in relative-effectiveness in the absence of directly comparative studies. At launch, the Scottish system uses economic analysis to understand the uncertainties and may restrict or not recommend when the committee judges there to be too much uncertainty given the price set by the manufacturer. Economic analysis is essential to control access where prices cannot be negotiated. The French system tends to more often recommend the medicine and will provide a price at launch that is reflective of the judgments of clinical-efficacy and uncertainty in the evidence. The French process then requires the manufacturer to collect further real life evidence in the presence of uncertainty for reassessment of listing at 5 years.

Another implication of the use of economic analysis by SMC is the need to use a generic measure of health benefits in cost-utility analysis. Where there are HRQOL benefits perceived by patients these may not be picked up by conventional clinical measures, and health benefits are underestimated by HAS (see the erlotinib case study). In other situations the formal economic analysis showed that although clinical benefits were present, they were not necessarily sufficient to justify, in terms of the cost-effectiveness, the price expected by the manufacturer leading to the medicine being not recommended (see the sorafenib case study). The fact that the UK price is determined ex ante by the manufacturer means that the appraisal by SMC is directly concerned with the value of the medicine. Economic analysis provides a clear framework in which issues of value can be explored quantitatively and transparently. In France HAS makes a recommendation based on a judgment of the clinical benefits of the medicine. Economic value is not addressed until the negotiation on price in the CEPS, and there it is considered implicitly.

In summary, the SMC is faced with a price and must judge for which patients the benefits are sufficiently great to justify reimbursement. On the other hand, the HAS makes a judgment on the clinical benefits of a medicine across its marketing authorization, and the CEPS negotiations (focused by the HAS judgment) determine the price worth paying for those benefits. The differences between the systems make price the main adjustment variable in France, as opposed to quantity (i.e., patient sub-groups) in Scotland. The two approaches provide different incentives to manufacturers seeking to innovate. France tends to offer higher sales volumes at a potentially lower price, while Scotland may offer higher initial prices, but for a restricted volume of sales.

CONCLUSION

This study provides some hypotheses and explanations for the differences observed in recommendations for a selected sample of medicines. However, the differences may be associated with contextual factors such as politics, cultural traditions, and local physician prescribing patterns rather than the analytical methods used or the agencies' processes. Without controlling for all factors, it is difficult to draw any conclusions on whether one reimbursement system is better than the other in delivering health benefits, controlling healthcare costs or incentivizing innovation. This would require further quantitative analysis of a larger sample of medicines and observation of usage rates and patient outcomes. Further research could explore the balance between the manufacturer (producer surplus) and patients (consumer surplus) by an analysis of prices and reimbursement decisions over the life cycle of the medicines in the two countries. Even if this were possible a study design, which controlled for all system differences would be difficult to achieve. A

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further limitation is that the study relies on the documentation, assuming that all important details are provided. Additionally, the HAS recommendations for which English translations are available may not be representative.

In December 2010, consultations were published in both countries for changes to the appraisal of medicines. The Department of Health in England[2] has published a consultation on a new value based approach (VBP) to the pricing of branded medicines in the UK to replace the PPRS (5). Consequently, several suggestions have been made for the operation of VBP in the UK (3;13;16;17). HAS published a consultation on procedures and methods for economic analysis (8). The consultations propose the introduction of price negotiation for the SMC and the introduction of economic analysis for HAS appraisal of medicines. This may result in convergence between the systems, reducing the differences in recommendations and access to medicines between the countries. The Scottish system will need to determine the details of price negotiations, agencies involved, other factors to be taken into account and how reassessment of the price could be undertaken. The French system will need to determine whether economic analysis is used at launch and/or at reassessment, the opportunity cost of healthcare resources and other factors. The forthcoming details of these process changes will influence the extent to which variation in recommendations is reduced and health is maximized in each country given their respective budget constraints.

SUPPLEMENTARY MATERIAL

Supplementary Table 1
Supplementary Table 2
Supplementary Table 3
Supplementary Table 4
Supplementary Table 5
Supplementary Table 6
www.journals.cambridge.org/thc2012019

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CONFLICTS OF INTEREST

Matthew Bending and John Hutton are employed by York Health Economics Consortium at the University of York and have received a grant to their institute from Pfizer Inc. Clare McGrath is employed by Pfizer Pharmaceuticals.

[2]The PPRS is a voluntary agreement between manufacturers in operation for over 50 years and works in conjunction with other measures to encourage cost-effective prescribing of medicines. The Department of Health in England consulted on a proposal to modify this scheme through value based pricing for the entire UK.

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